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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,128	09/20/2006	Kimihiro Mabuchi	19461-005US1 548062	4588
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EXAMINER				
MENON, KRISHNAN S				
ART UNIT		PAPER NUMBER		
1797				
NOTIFICATION DATE		DELIVERY MODE		
04/27/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/599,128

Applicant(s)

MABUCHI ET AL.

Examiner

Krishnan S. Menon

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claims 1-15 and 17-21 are pending as amended 4/14/09. Claims 17-21 are withdrawn.

Effective date – 3/22/04.

Terminal Disclaimer

The terminal disclaimer filed on 4/14/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on 10/599,167 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

Claims 1-15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shimagaki et al (US 6,103,117)

Claim interpretation: Applicant's claim 1 recite a perm-selective membrane made from polysulfone and polyvinyl pyrrolidone. The remaining limitations of claim 1 describe how the membrane performs with respect to bovine blood, in terms of albumin sieving coefficient over certain time periods when the membrane is operated with certain fluxes.

Shimagaki teaches hollow fiber membranes made from polysulfone and PVP – see examples, with about 40 microns thickness, about 33% PVP content. This

reference does not explicitly state the sieving coefficient or albumin clearance, but teaches albumin permeabilities of about 1.2% or less (examples, abstract).

Membrane is asymmetric, which means it has a thin skin layer inherently the range claimed.

The membrane properties of albumin sieving coefficient, etc., would be inherent, because the membrane is made of the same material, and has the same or similar structure. More over, the membrane is made for the same application as that of the applicant's.

Cross-linked – see column 11, starting at line 42.

Fiber diameter and thickness – see about 40 microns in example 7. The fiber is spun from a 0.3mm OD/0.2mm ID nozzle in all examples – therefore, the fiber thickness would be within the range claimed.

Aperture ratio: this is also an inherent characteristic of the membrane from the way it is made, and since the applicant's membrane is made the same way as that of the reference, it is inherent in the reference.

Regarding the polyvinyl pyrrolidone content of the blood-contacting and non-blood—contacting surfaces(the D/C ratio), applicant's disclosure (pre-grant publication, paragraph 0147-0148) describes the orientation of PVP as related to the spinning nozzle dimensions, as well as the molecular weight of the PVP (paragraph 0082), and the composition of the internal liquid (paragraph 0060). The reference teaches spinning nozzle dimensions, molecular weights within this range and the inner solution of the same composition, and therefore, this characteristic also is inherent in the membrane of

the reference. Similarly, since the compositions and the method of making is the same, the mechanical strength of the membrane also would be in the same range as claimed.

Specifically, see the teaching in column 6, lines 49-67.

Response to Arguments

Applicant's arguments filed 4/14/09 have been fully considered but they are not persuasive.

Regarding the D/C ratio as claimed: the argument traversing the rejection of this element is not commensurate in scope with the rejection, and applicant is attacking the wrong reasons.

First of all, 33% PVP content – 18 parts polysulfone and 9 parts PVP would give $18/27 = 67\%$ polysulfone and $9/27 = 33\%$ PVP: examples 1 and 2. Example 5 has PVP = $9/(19+9) = 32\%$. However, this is immaterial since the claims recite only the ratio D/C as >1.1 , which is achieved by differential extraction between the inner and outer surface by adjusting the core fluid and the coagulation bath/wash solutions. Applicant has not provided any evidence to show that the Reference membrane would not meet this condition.

Regarding the third point, that is the Albumin sieving coefficient, arguments are not persuasive, and applicant has failed to produce any evidence that the reference membrane would not display the characteristics cited.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797